

Announcement of an application for approval of an additional indication for therapeutic agent for endometriosis, “Dinagest Tab. / OD Tab.” in Japan

This material is an English translation of the press release issued on January 27, 2016 in Japanese, and the Japanese release is given priority regarding content and interpretation.

January 27, 2016

Mochida Pharmaceutical Co., Ltd. (Head office: Tokyo, Japan, President: Naoyuki Mochida, hereinafter: “Mochida”) announced that Mochida has filed an application for approval of an additional indication for “Dinagest Tab. 1mg” and “Dinagest OD Tab. 1mg” (generic name: dienogest), therapeutic agents for endometriosis, for the reduction of pain caused by adenomyosis with the Japanese Ministry of Health, Labour and Welfare (MHLW) on January 27, 2016.

Adenomyosis is a disease in which the endometrium-like tissue grows within the myometrium. Patients with adenomyosis often complain of strong menstrual pain that may affect daily living. The peak age of onset is 40-49 years old. Reportedly, 15% to 20% of perimenopausal women have this disease. Curative treatment is surgery (surgical therapy), but if a patient wishes to maintain fertility, there is an option of drug therapy (hormone therapy) to improve clinical symptoms. However, at present, there is no drug with an indication for adenomyosis, and therefore, a therapeutic agent that can be safely used for a long time has been anticipated.

Dienogest was in-licensed from Jenapharm, Germany, a subsidiary of Bayer Pharma AG, and Mochida developed it as a therapeutic agent for endometriosis, and has marketed since 2008. As dienogest acts to selectively activate progesterone receptors so as to inhibit ovarian function and the proliferation of endometrial cells, it is also expected to have efficacy on adenomyosis.

Mochida is striving to obtain approval for the application in order to contribute to improving the QOL of women with adenomyosis.

The impact of the application on the consolidated financial results of Mochida will be minor for the near term.